

K954852

**510(k) Summary of
Safety and Effectiveness**

1. **Manufacturer/ Submitter**
Marquette Electronics, Inc.
8200 West Tower Avenue
Milwaukee, WI 53223 U.S.A.

Establishment Registration Number: 2124823

Contact Name/ Telephone Number:

Dianne Schmitz
Corporate Regulatory Affairs
Marquette Electronics, Inc.

Phone: (414) 362-3230

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2. **General Device Information**

Common/ Usual Name

This device is commonly known as a patient monitoring system.

Trade/ Proprietary Name

Marquette Electronics, Inc's trade/ proprietary name for this device is the Solar 9000 Anesthesia Information Monitor.

Classification Name(s)

The Marquette Solar 9000 Anesthesia Information Monitor's classification names, classification panels, and regulation citations include:

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| * 21 CFR 868.1400 Analyzer, Gas, Carbon-Dioxide, Gaseous-Phase | 73CCK |
| * 21 CFR 868.1500 Analyzer, Gas, Enflurane, Gaseous-Phase (Anesthetic Conc.) | 73CBQ |
| * 21 CFR 868.1620 Analyzer, Gas, Halothane, Gaseous-Phase, (Anesthetic Conc.) | 73CBS |
| * 21 CFR 868.1690 Analyzer, Gas, Nitrogen Gaseous-Phase | 73CCI |
| * 21 CFR 868.1700 Analyzer, Gas, Nitrous-Oxide, Gaseous-Phase, (Anesthetic Conc.) | 73CBR |
| * 21 CFR 868.1720 Analyzer, Gas, Oxygen, Gaseous-Phase | 73CCL |
| * 21 CFR 868.2375 Monitor, Breathing Frequency | 73BZQ |
| * 21 CFR 870.1025 Detector and Alarm, Arrhythmia | 74DSI |
| * 21 CFR 870.1100 Monitor, Blood Pressure, Indwelling | 74CAA |
| * 21 CFR 870.1130 Monitor, Blood Pressure, Non-Indwelling | 74BXD |

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- * 21 CFR 870.1435 Cardiac Output, Thermal (Balloon Type Catheter) 74KFN
- * 21 CFR 880.2910 Monitor, Temperature (with probe) 80BWX
- * 21 CFR 870.2300 Monitor, Cardiac (Incl. cardiometer & rate alarm) 74DRT
- * 21 CFR 870.2700 Oximeter, Pulse 74BWS

Device Classification

Devices monitoring similar parameters, except the "Detector and Alarm, Arrhythmia" parameter, have been determined to be Class II devices according to the Anesthesiology and/ or Cardiovascular Device Classification Panels. The "Detector and Alarm, Arrhythmia" parameter is a Class III parameter. Because the Marquette Solar 9000 Anesthesia Information Monitor may acquire and display data from a module that may include this Class III parameter, it is believed that FDA may classify the system as a Class III device.

Performance Standards

Performance standards (Section 514 of the Act) have not yet been established for the device that is the subject of this premarket notification submission.

3. Legally Marketed Predicate Device

The Marquette Solar 9000 Anesthesia Information Monitor is substantially equivalent, with similar indications for use to the following devices which are currently legally marketed and in commercial distribution:

- * K900598 Tramscope System

4. Device Description

The Marquette Solar 9000 Anesthesia Information Monitor is a patient monitoring system that is designed to display patient physiological data that is received from the Marquette Electronic's Tram-Net (Unity) network, Tram individual and multi-parameter data acquisition modules (K900540), and other compatible modules, as referenced within the Premarket Notification Submission.

The data and information these modules acquire includes, but is not limited to: Electrocardiography (ECG) information, QRS and arrhythmia detection, heart rate calculation, ST-segment analysis, cardiac output, wedge determination, and systolic, diastolic, and mean pressure measurements. Additional data and information that these modules acquire includes: respiratory rate detection and computation, detection of a no breath (or apneic) period, respiratory and anesthesia gas parameters, ventilation parameters, pulse oximetry values, plethysmograph values, and temperature measurements. The Solar 9000 Anesthesia Information Monitor is designed to display ECG and pressure and respiratory waveforms generated from the network and the various acquisition modules.

The operator uses the system to interact with the acquired data via a color display device. This interaction includes: selecting which waveforms or parameters are displayed, display and review of trended data, silencing alarms, adjusting parameter alarm levels, or printing selected data.

5. Intended Use

Use of the Marquette Solar 9000 Anesthesia Information Monitor is intended for patient populations including: adult, pediatric, and/ or neonatal.

Use of the Marquette Solar 9000 Anesthesia Information Monitor is not recommended for use in patient's home or residence, during patient transport, or when it has not been ordered by a physician or other qualified personnel.

Use of the Marquette Solar 9000 Anesthesia Information Monitor is intended for operating room (OR), post anesthesia recovery, critical care, surgical intensive care, respiratory intensive care, coronary care, medical intensive care, pediatric intensive care, or neonatal intensive care. These departments are typically located in hospitals or may be located in outpatient clinics or free standing surgical centers. It is intended for use by physicians, physician assistants, registered nurses, certified registered nurse anesthetists, or other hospital personnel trained in the use of the equipment.